



1645

PATENT  
Attorney Docket No.: JHU1680-2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

P#17

Applicants: Germino et al. Art Unit: 1645  
Application No.: 09/904,968 Examiner: S. Sakelaris  
Filed: July 13, 2001  
Title: DETECTION AND TREATMENT OF POLYCYSTIC KIDNEY DISEASE

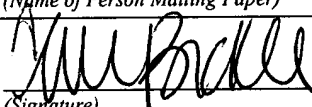
Commissioner for Patents  
Washington, D.C. 20231

TRANSMITTAL SHEET

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Transmitted herewith for the above-identified application please find:

1. Information Disclosure Statement (2 pages);
2. Form PTO-1449 (1 page);
3. Seven (7) Other Documents;
4. A copy of the International Search Report dated December 5, 2002 (12 pages); and
5. Return receipt postcard.

CERTIFICATION UNDER 37 CFR §1.8	
I hereby certify that the documents referred to as enclosed herein are being deposited with the United States Postal Service as first class mail on this date, <b>February 19, 2003</b> , in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231.	
Carrie E. Bickle (Name of Person Mailing Paper)	
 (Signature)	February 19, 2003 (Date)

In re Application of:

Germino et al.

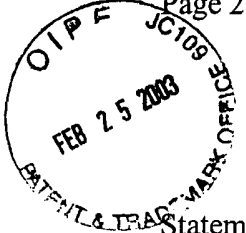
Application No.: 09/904,968

Filed: July 13, 2001

Page 2

PATENT

Attorney Docket No.: JHU1680-2



No fee is deemed necessary in connection with the filing of this Information Disclosure Statement as each item of information contained in this statement was cited in a communication from a foreign patent office in a counterpart foreign application, the communication being dated December 5, 2002, which is not more than three months prior to the filing of this statement. However, if any fee is required, authorization is hereby given to charge Deposit Account No. 50-1355.

Respectfully submitted,

Date: February 19, 2003

A handwritten signature in black ink, appearing to read "Richard J. Imbra".

Richard J. Imbra

Registration No. 37,643

Telephone: (858) 677-1496

Facsimile: (858) 677-1465

**USPTO CUSTOMER NUMBER 28213**  
**GRAY CARY WARE & FREIDENRICH LLP**  
4365 Executive Drive, Suite 1100  
San Diego, CA 92121-2133



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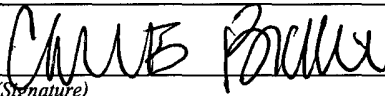
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**INFORMATION DISCLOSURE STATEMENT**

Sir:

In accordance with 37 C.F.R. 1.97, enclosed are references relating to the above-identified application. For the convenience of the Examiner, the references are listed on the attached Form PTO-1449. A copy of references AB – AD and AF – AI are enclosed herewith. References AA, AE and AK – AL were previously submitted in an Information Disclosure Statement for the above-identified application. A copy of the International Search Report listing the references cited from a communication from a foreign patent office also is enclosed.

It is respectfully requested that these references be considered in the examination of this application and their consideration be made of written record in the application file.

CERTIFICATION UNDER 37 CFR §1.8	
I hereby certify that the documents referred to as enclosed herein are being deposited with the United States Postal Service as first class mail on this date, <b>February 19, 2003</b> , in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231.	
Carrie E. Bickle (Name of Person Mailing Paper)	
 (Signature)	<b>February 19, 2003</b> (Date)

In re Application of:

Germino et al.

Application No.: 09/904,968

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Page 2

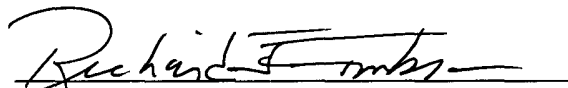
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Telephone: (858) 677-1496

Facsimile: (858) 677-1465

**USPTO CUSTOMER NUMBER 28213**  
GRAY CARY WARE & FREIDENRICH LLP  
4365 Executive Drive, Suite 1100  
San Diego, CA 92121-2133



<b>FORM PTO-1449</b> U.S. Department of Commerce Patent and Trademark Office	<b>Docket No. (Optional)</b> JHU1680-2	<b>Serial No.:</b> 09/904,968
	<b>Applicant(s):</b> Germino et al.	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>	<b>Filing Date:</b> July 13, 2001	<b>Group Art Unit:</b> 1645

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### U.S. PATENT DOCUMENTS

EXAM. INITIALS	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
AA	6,071,717	06/06/2000	Klinger et al.			

### FOREIGN PATENT DOCUMENTS

EXAM. INITIALS	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION (YES/NO)

### OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages)

4	AB	Neophytou, et al., "Detection of a novel nonsense mutation and an intragenic polymorphism in the PKD1 gene of a Cypriot family with autosomal dominant polycystic kidney disease," <i>Human Genet</i> 98: 437-442 (1996).
2	AC	Peral, et al., "Screening the 3' Region of the Polycystic Kidney Disease 1 (PKD1) Gene Reveals Six Novel Mutations," <i>Am. J. Human Genet.</i> 58: 86 - 96 (1996).
3	AD	Perrichot, et al., "DGGE Screening of PKD1 gene reveals novel mutations in a large cohort of 146 unrelated patients," <i>Hum Genet</i> 105: 231-239 (1999).
4	AE	Phakdeekitcharoen, Bunyong et al., "Mutation Analysis of the Entire Replicated Portion of PKD1 Using Genomic DNA Samples," <i>J. Am. Soc. Nephrol.</i> , Vol. 12, 2001, pgs. 955-963.
5	AF	Roelfsema, et al., "Mutation Detection in the Repeated Part of the PKD1 Gene," <i>Am. J. Hum. Genet.</i> 61: 1044-1052 (1997).
6	AG	Thomas et al., "Identification of Mutations in the Repeated Part of the Autosomal Dominant Polycystic Kidney Disease Type 1 Gene, PKD1, by Long-Range PCR," <i>Am. J. Hum. Genet.</i> 65: 39-49 (1999).

EXAMINER	DATE CONSIDERED
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EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

PATENT DOCKETING  
DEC 10 2002

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To:  
GRAY CARY WARE & FRIEDENRICH LLP  
Attn. Haile, Lisa A.  
4365 Executive Drive, Suite 1100  
San Diego, CA 92121-2133  
UNITED STATES OF AMERICA

INVITATION TO PAY ADDITIONAL FEES

(PCT Article 17(3)(a) and Rule 40.1)

REGISTERED MAIL

Applicant's or agent's file reference JHU1680W0		Date of mailing (day/month/year) 05/12/2002
International application No. PCT/US 01/ 22035		PAYMENT DUE within 45 <del>xxxx</del> days from the above date of mailing
Applicant THE JOHNS HOPKINS UNIVERSITY SCHOOL OF MEDICINE		International filing date (day/month/year) 13/07/2001

1. This International Searching Authority

- (i) considers that there are 84 (number of) inventions claimed in the international application covered by the claims indicated ~~XXXX~~ on the extra sheet:

and it considers that the international application does not comply with the requirements of unity of invention (Rules 13.1, 13.2 and 13.3) for the reasons indicated ~~XXXX~~ on the extra sheet:

- (ii) ☒ has carried out a partial international search (see Annex) ☐ will establish the international search report on those parts of the international application which relate to the invention first mentioned in claims Nos.:

see Form PCT/ISA/206

- (iii) will establish the international search report on the other parts of the international application only if, and to the extent to which, additional fees are paid

2. The applicant is hereby invited, within the time limit indicated above, to pay the amount indicated below:

EUR 945,00 <sup>(955.00 us)</sup> x 83 = EUR 78.435,00  
Fee per additional invention      number of additional inventions      total amount of additional fees

Or, \_\_\_\_\_ x \_\_\_\_\_ = \_\_\_\_\_

The applicant is informed that, according to Rule 40.2(c), the payment of any additional fee may be made under protest, i.e., a reasoned statement to the effect that the international application complies with the requirement of unity of invention or that the amount of the required additional fee is excessive.

3. ☒ Claim(s) Nos. s. PCT/ISA/206 have been found to be unsearchable under Article 17(2)(b) because of defects under Article 17(2)(a) and therefore have not been included with any invention.

Name and mailing address of the International Searching Authority



European Patent Office, P.B. 5818 Patentlaan 2  
NL-2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Heike Zoglauer

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-9,12-14,16-19,25,26,28-42,44-53,55-61,  
63-65 (all partially)

Invention 1:

A primer comprising a nucleotide sequence substantially identical to SEQ ID No. 3 or 4; a solid matrix, comprising said primer immobilised on the solid matrix; a kit comprising said primer; a primer pair comprising SEQ ID Nos. 3 and 4; a method of detecting the presence or absence of a mutation in a PKD1 polynucleotide in a sample using said primer pair; a method of identifying a subject at risk for a PKD1-associated disorder using said primer pair; a method of diagnosing a PKD1-associated disorder in a subject using said primer pair; a kit comprising said primer pair.

2. Claims: 1-9,12-14,16-19,25,26,28-42,44-53,55-61,  
63-65 (all partially)

Inventions 2-6:

Idem as invention 1, but for each of the inventions 2-6 limited to one of the following pairs of SEQ ID Nos. 5 and 6, 7 and 8, 9 and 10, 13 and 14, 15 and 16.

3. Claims: 1-9,12-14,16-19,25,26,28-42,44-53,55-61,  
63-65 (all partially)

Invention 7:

A primer comprising a nucleotide sequence substantially identical to SEQ ID No. 12; a solid matrix, comprising said primer immobilised on the solid matrix; a kit comprising said primer; a primer pair comprising SEQ ID Nos. 11 and 12; a method of detecting the presence or absence of a mutation in a PKD1 polynucleotide in a sample using said primer pair; a method of identifying a subject at risk for a PKD1-associated disorder using said primer pair; a method of diagnosing a PKD1-associated disorder in a subject using said primer pair; a kit comprising said primer pair.

4. Claims: 1-9,12-14,16-19,25,26,28-42,44-53,55-61,  
63-65 (all partially)

Invention 8:

A primer comprising a nucleotide sequence substantially identical to SEQ ID No. 17; a solid matrix, comprising said

primer immobilised on the solid matrix; a kit comprising said primer; a primer pair comprising SEQ ID Nos. 17 and 18; a method of detecting the presence or absence of a mutation in a PKD1 polynucleotide in a sample using said primer pair; a method of identifying a subject at risk for a PKD1-associated disorder using said primer pair; a method of diagnosing a PKD1-associated disorder in a subject using said primer pair; a kit comprising said primer pair.

5. Claims: 1-7,10,11,15-19,25,27-42,44,46-61,  
63-65 (all partially)

Invention 9:

A primer comprising a nucleotide sequence substantially identical to SEQ ID No. 19 or 20; a solid matrix, comprising said primer immobilised on the solid matrix; a kit comprising said primer; a primer pair comprising SEQ ID Nos. 19 and 20; a method of detecting the presence or absence of a mutation in a PKD1 polynucleotide in a sample using said primer pair; a method of identifying a subject at risk for a PKD1-associated disorder using said primer pair; a method of diagnosing a PKD1-associated disorder in a subject using said primer pair; a kit comprising said primer pair.

6. Claims: 1-7,10,11,15-19,25,27-42,44,46-61,  
63-65 (all partially)

Inventions 10-51:

Idem as invention 9, but for each of the inventions 10-51 limited to one of the further combinations of SEQ ID Nos. proposed in claim 11.

7. Claims: 20-24,62,66 (all partially)

Invention 52:

An isolated polynucleotide, comprising a contiguous sequence of at least about ten nucleotides substantially identical to a nucleotide sequence of SEQ ID No. 1 or a nucleotide sequence complementary thereto, the contiguous nucleotide sequence comprising with respect to SEQ ID No. 1 a T at nucleotide position 474; a vector comprising said polynucleotide; a host cell containing said vector; a solid matrix, wherein said polynucleotide is immobilised on the solid matrix; a method of detecting the presence of a mutant PKD1 polynucleotide in a sample using said polynucleotide; a kit containing said polynucleotide.

8. Claims: 20-24,62,66 (all partially)

Inventions 53-83:

Idem as invention 52, but for each of the inventions 53-83 limited to one of the further variants proposed in claim 20.

9. Claim : 67 (completely)

Invention 84:

A kit comprising an antibody that specifically binds to a mutant PKD1 polynucleotide.

1. The only identifiable technical feature that all 84 inventions have in common is the PKD1 gene. Inventions 1-51 all propose primers with specificity for the PKD1 gene. Inventions 52-83 all relate to variations of the PKD1 gene.

2. EMBL Accession no. L39891 (D1) and US 6071717 (D2) disclose the PKD1 gene and the PKD1 protein. D2; Watnick et al., Am. J. Hum. Genet. 65:1561 (1999)(D3), Watnick et al., Hum. Mol. Genet. 6:1473 (1997) (D4); Watnick et al. Mol. Cell 2:247 (1998) (D5); Peral et al., Am. J. Hum. Genet. 58:86 (1996) (D6); Roelfsema et al., Am. J. Hum. Genet. 61:1044 (1997) (D7); Neophytou et al., Hum. Genet. 98:437 (1996) (D8); Perrichot et al., Hum. Genet. 105:231 (1999) (D9); Turco et al., Hum. Mol. Genet. 4:1331 (1995) (D10); and Thomas et al., Am. J. Hum. Genet. 65:39 (1999) (D11) disclose primers specific for the PKD1 gene. Furthermore D3-D9 disclose variants of the PKD1 gene and methods for determining said variants.

3. In view of the prior art represented by D1-D11 the problem of the underlying application can be defined i) with respect to inventions 1-51, as the provision of further primers specific for the PKD1 gene; ii) with respect to inventions 52-83, as the provision of further variants of the PKD1 gene; and iii) with respect to invention 84 as the provision of an antibody specific for a mutant PKD1 polypeptide.

4. Each of the primers listed above under inventions 1-51 represents an independent solution concerning the problem given under item 3.i). Solution 1 is the provision of a primer comprising a nucleotide sequence substantially identical to SEQ ID No. 3 or 4; a primer pair comprising SEQ ID Nos. 3 and 4; and methods using said primer pair. The solutions 2-51 are each the provision of a different primer and primer pair. Each of the PKD1 gene variants listed under inventions 52-83 represents an independent solution to the problem given under item 3.ii). Solution 52 is the provision of a PKD1 variant with a T at nucleotide position 474 and a method using said variant. The solutions 53-83 are each the provision of a different PKD1 gene variant. Invention 84 provides a solution to the problem of providing an antibody specific for a mutant PKD1 polypeptide.

5. In view of the fact that the PKD1 gene and variants thereof, as well as primers and primer pairs specific for the PKD1 gene are already known from the prior art, due to the essential differences in primary structure of both the PKD1 gene variants and the different primers specific for the PKD1 gene; and due to the fact that no other technical

features can be distinguished which, in the light of the prior art, could be regarded as special technical features common to the above solutions, the ISA is of the opinion that there is no single inventive concept underlying the plurality of said 84 solutions in the sense of R. 13.1 PCT. Consequently, there is a lack of unity, and different inventions, not belonging to a common inventive concept are formulated as different subjects on the communication pursuant to Art. 17(3)(a) PCT.

6. The ISA has searched the first invention.

## FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 206

Continuation of Box 3.

Claims Nos.: 1-5, 7, 12-25, 28-42, 44, 46-49, 53-66

1. Present claims 1-5, 7, 12-25, 28-42, 44, 46-49, 53-66 relate to an extremely large number of possible primers/methods. In fact, the claims contain so many options and possible permutations that a lack of clarity and conciseness within the meaning of Article 6 PCT arises to such an extent as to render a meaningful search of the claims impossible.

1.1 Consequently, the search with respect to invention 1 i.e. parts of claims 1-5, 12-14, 16-19, 25, 28-42, 44, 46-49, 53, 55-61, and 63-65 has been carried out for those parts of the application which do appear to be clear and concise, namely primers defined by the primer pairs given in claim 9, as well as methods using said primer pairs.

1.2 The same would apply to inventions 2-9, should the applicant decide to have said inventions searched.

1.3 Should the applicant decide to have inventions 9-51 searched, the subject-matter of claims 1-5, 7, 15-19, 25, 28-42, 44, 46-49, 53-61, and 63-65 will only be searched insofar as it relates to primers defined by the primer pairs given in claim 10, as well as methods using said primer pairs.

1.4 Should the applicant decide to have inventions 52-83 searched, the subject-matter of claims 20-24, 62, and 66 will only be searched insofar as it relates to variants of the PDK1 gene as defined by one of the changes with respect to SEQ ID No. 1 given in claim 20, as well as methods using said variants.

1.5 As it is furthermore not clear which combination of a polynucleotide according to claim 20 with an amplification product obtained with a primer pair according to claim 7 allows to identify the presence or absence of a mutation in said amplification product, the subject-matter of claim 43 was considered to be too unclear for a search to be carried out.

2. Moreover, present claims 1-5 and 63-65 relate to primers defined inter alia by reference to the following parameters:

P1: a 5' region selectively hybridising to a PDK1 gene sequence and, optionally, to a PDK1 gene homolog sequence

P2: a 3' region selectively hybridising to a PDK1 gene sequence, and not a PDK1 gene homolog sequence

The use of these parameters in the present context is considered to lead to a lack of clarity within the meaning of Article 6 PCT. It is impossible to compare the parameters the applicant has chosen to employ with what is set out in the prior art. The lack of clarity is such as to render a meaningful complete search impossible. Consequently, the search

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 206

has been restricted to:

Primers defined by the primer pairs given in claim 9, as well as methods using said primer pairs.

In case of a further search with respect to inventions 9-51, primers defined by the primer pairs given in claim 10, as well as methods using said primer pairs will be searched.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

1. The present communication is an Annex to the invitation to pay additional fees (Form PCT/ISA/206). It shows the results of the international search established on the parts of the international application which relate to the invention first mentioned in claims Nos.:
- see 'Invitation to pay additional fees'
2. This communication is not the international search report which will be established according to Article 18 and Rule 43.
3. If the applicant does not pay any additional search fees, the information appearing in this communication will be considered as the result of the international search and will be included as such in the international search report.
4. If the applicant pays additional fees, the international search report will contain both the information appearing in this communication and the results of the international search on other parts of the international application for which such fees will have been paid.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DATABASE EMBL 'Online! EBI; 4 May 1995 (1995-05-04) WARD ET AL.: "Homo sapiens polycystic kidney disease-associated protein (PKD1) gene" retrieved from HTTP://WWW.EBI.AC.UK Database accession no. L39891 XP002217564 cited in the application the whole document	1-9, 12-14, 16-19, 25,26, 28-42, 44-53, 55-61, 63-65
X	US 6 071 717 A (DACKOWSKI WILLIAM ET AL) 6 June 2000 (2000-06-06) cited in the application  column 11, line 39 - line 54 example 5 SEQ ID No. 2 claims 2,7,9	1-9, 12-14, 16-19, 63-65
Y		25,26, 28-42, 44-53, 55-61
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

\* Special categories of cited documents :

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

- \*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- \*G\* document member of the same patent family

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	<p>WATNICK TERRY ET AL: "Mutation detection of PKD1 identifies a novel mutation common to three families with aneurysms and/or very-early-onset disease." AMERICAN JOURNAL OF HUMAN GENETICS, vol. 65, no. 6, December 1999 (1999-12), pages 1561-1571, XP002217557 ISSN: 0002-9297 cited in the application page 1562, right-hand column, paragraph 2 -page 1563, right-hand column, paragraph 1 tables 1-4</p>	<p>25,26, 28-42, 44-53, 55-61</p>
Y	<p>WATNICK TERRY J ET AL: "An unusual pattern of mutation in the duplicated portion of PKD1 is revealed by use of a novel strategy for mutation detection." HUMAN MOLECULAR GENETICS, vol. 6, no. 9, 1997, pages 1473-1481, XP002217558 ISSN: 0964-6906 cited in the application page 1479, right-hand column, paragraph 5 -page 1480, right-hand column, paragraph 1 tables 1,2</p>	<p>25,26, 28-42, 44-53, 55-61</p>
Y	<p>WATNICK TERRY J ET AL: "Somatic mutation in individual liver cysts supports a two-hit model of cystogenesis in autosomal dominant polycystic kidney disease." MOLECULAR CELL, vol. 2, no. 2, August 1998 (1998-08), pages 247-251, XP002217559 ISSN: 1097-2765 cited in the application page 250, right-hand column, paragraph 4 -page 251, left-hand column, paragraph 2 table 1</p>	<p>25,26, 28-42, 44-49, 53,55-61</p>
Y	<p>PERAL B ET AL: "SCREENING 3' REGION OF THE POLYCYSTIC KIDNEY DISEASE 1 (PKD1) GENE REVEALS SIX NOVEL MUTATIONS" AMERICAN JOURNAL OF HUMAN GENETICS, UNIVERSITY OF CHICAGO PRESS, CHICAGO,, US, vol. 58, no. 1, January 1996 (1996-01), pages 86-96, XP001018250 ISSN: 0002-9297 page 87, right-hand column, paragraph 5 -page 89, right-hand column, paragraph 1 table 1 figures 1-6</p>	<p>25,26, 28-42, 44-53, 55-61</p>

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	NEOPHYTOU PAVLOS ET AL: "Detection of a novel nonsense mutation and an intragenic polymorphism in the PKD1 gene of a Cypriot family with autosomal dominant polycystic kidney disease." HUMAN GENETICS, vol. 98, no. 4, 1996, pages 437-442, XP002217560 ISSN: 0340-6717 abstract page 438, left-hand column, paragraph 4 -right-hand column, paragraph 2 figures 1-4 table 1	25,26, 28-42, 44-53, 55-61
Y	----- PERRICHOT R A ET AL: "DGGE screening of PKD1 gene reveals novel mutations in a large cohort of 146 unrelated patients." HUMAN GENETICS, vol. 105, no. 3, 1999, pages 231-239, XP002217561 ISSN: 0340-6717 page 233, left-hand column, paragraph 5 -right-hand column, paragraph 1 tables 1-3	25,26, 28-42, 44-53, 55-61
Y	----- TURCO ALBERTO E ET AL: "A novel nonsense mutation in the PKD1 gene (C3817T) is associated with autosomal dominant polycystic kidney disease (ADPKD) in a large three-generation Italian family." HUMAN MOLECULAR GENETICS, vol. 4, no. 8, 1995, pages 1331-1335, XP001117586 ISSN: 0964-6906 abstract page 1334, left-hand column	25,26, 28-42, 44-49, 53,55-61
Y	----- THOMAS RUTH ET AL: "Identification of mutations in the repeated part of the autosomal dominant polycystic kidney disease type 1 gene, PKD1, by long-range PCR." AMERICAN JOURNAL OF HUMAN GENETICS, vol. 65, no. 1, July 1999 (1999-07), pages 39-49, XP002217562 ISSN: 0002-9297 page 40, right-hand column, paragraph 3 -page 42, left-hand column, paragraph 1 tables 2-4	25,26, 28-42, 44-49, 53,55-61
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	ROELFSEMA JEROEN H ET AL: "Mutation detection in the repeated part of the PKD1 gene." AMERICAN JOURNAL OF HUMAN GENETICS, vol. 61, no. 5, November 1997 (1997-11), pages 1044-1052, XP002217563 ISSN: 0002-9297 page 1046, left-hand column, paragraph 1 - paragraph 2 tables 1,2 -----	25,26, 28-42, 44-53, 55-61
P,X	PHAKDEEKITCHAROEN BUNYONG ET AL: "Mutation analysis of the entire replicated portion of PKD1 using genomic DNA samples." JOURNAL OF THE AMERICAN SOCIETY OF NEPHROLOGY, vol. 12, no. 5, May 2001 (2001-05), pages 955-963, XP002217652 ISSN: 1046-6673 the whole document -----	1-9, 12-14, 16-19, 25,26, 28-42, 44-53, 55-61, 63-65

# Patent Family Annex

Information on patent family members

International Application No

PCT/US 01/22035

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